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VIA COURIER

March 26, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures-Scope and Application"
Docket Numbers 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539.

Ladies and Gentlemen,

Reference is made to Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures-Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide that was published in the Federal Register on February 25, 2003.

Cyberonics, Inc. has reviewed the draft guidance document and believes that in addition to the requirements of 21 CFR Part 11 that have been identified as requirements that will be enforced with discretion, we ask that enforcement discretion also be exercised in regard to 21 CFR Part 11, 11.10 (e). We believe that 21 CFR Part 11, 11.10 (e) should only apply to changes made through the application and API interfaces.

Changes made directly to the underlying database records by database administrators and others with direct access to the record must be documented and controlled through security, but the changes need not be automatically captured by the electronic audit trail function of the application.

00D-1539

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We feel that the imposition of this requirement would significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted. Audit trail technology is actively incorporated at the application level but is at its infancy when trying to audit trail the activities of those technologist who are responsible for maintaining, supporting and fixing the underlying databases and records of those applications.

We feel that without this change, technology adoption and use would be unnecessarily restricted without providing a significant public health benefit.

Thank you for giving us the opportunity to present this important matter to your attention. Should you have any questions or require further clarification, please contact Daniel Stoller, Software Reliability Engineer at 281-727-2606, or at daniel.stoller@cyberonics.com.

Sincerely,

Alan Totah

Alan Totah
Vice President, Regulatory and Quality

cc: Bernie Liebler
Director, Technology and Regulatory Affairs
Advamed